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computed based on your methodology, the rate of pain with the autologous slings was actually higher than the midurethral sling; do you remember that?
A. Leg pain?
Q. You didn't break it down by leg pain, you just wrote pain.
A. Is whatever an answer? I'll just say whatever.
Q. Bladder perforation, you see pubovaginal had a 2.3 percent?
A. Yes, I do.
Q. Now, I understand -- didn't you tell me earlier you never hit the bladder with a pubovaginal sling?
A. Twice.
Q. Twice you did?
A. In well over 2,000.
Q. But, apparently, other folks have a much higher incidence of hitting the bladder doing a pubovaginal sling than you, correct?
A. According to this, yeah. As I said, before I accept

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any of these things as valid, I would want to read the studies.
Q. That was based on 14 pubovaginal studies involving over a thousand patients, correct?
A. Yes.
Q. Your knowledge of the SGS and the way -- you're familiar with the SGS, and they've come out with systematic reviews over the years on different topics pertaining to female pelvic medicine?
A. Yes.
Q. And you found those reviews to be reliable?
A. I don't know. I really haven't paid that much attention to it. But, you know, the data is only reliable as the methodology for the studies. And I said repeatedly that, in my judgment, the methodology for looking at these complications is seriously flawed and I'm not sure. And these are -- you know, I would just have to

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say.
MR. SNELL: Let's take a short break, because I do have to use the restroom.
- - -
(Whereupon, a brief recess was taken.)
- - -
BY MR. SNELL:
Q. Doctor, in your report, you talk about chronic mesh pain syndrome. Is that a recognized diagnostic code that's used in billing and assessments?
A. You know, I'm sorry, I don't know.
Q. Do you do any transobturator type procedures in your practice?
A. No, I don't.
Q. Would you ever consider performing a transobturator autologous sling?
A. No.
Q. Why not?

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A. I don't see any advantage to it. I mean, it's a -- I just don't see any advantage.
Q. Are there risks of operating in the transobturator space that are unique or different than operating in the retropubic space?
A. Sure. All the neuropathies and the thigh pains that we see.
Q. Can dissecting through the obturator space cause neuropathies?
A. If anything, it's possible.
Q. If you were going to do a transobturator autologous sling, would you anticipate there being a risk of groin pain or thigh pain?
A. It's totally hypothetical. I wouldn't do it.
Q. But knowing the space and the area, the anatomy, would you anticipate that there would be a risk of groin and thigh pain?
A. Well, only because of the experience of the transobturator mesh, to

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the extent that -- I mean, it's pretty clear to me that the obturator nerve doesn't have to be exactly where it's supposed to be.

Again, it's a blind procedure.

Q. Do you believe that case reports are among the lowest form of medical evidence?

A. Not for complications, I don't.

Q. Why is that?

A. Because they exist. If one person -- if the complications -- to a certain extent, I think they are one of the highest forms; either case reports or case series of complications, because there's no other way to accrue them.

Q. Case reports and case series, though, don't tell you the incidence or probability of the complication, correct?

A. Correct.

Q. And, for example, in the

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Abbott study that you cite to, that was a case series of patients who had complications, correct?

A. I need to see the paper again. It's been a long time.

Q. You recall they went to tertiary care center?

A. This is the one from three groups, Cincinnati?

MS. FITZPATRICK: They'll get it for you, if you don't remember.

MR. SNELL: I'm looking for it.

THE WITNESS: If I can't answer a general question, I'll tell you.

BY MR. SNELL:

Q. Do you recall the Abbott study, though, was a paper that reported on a series of patients who had reported mesh complications --

A. I do.

Q. -- who were evaluated at

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four U.S. tertiary referral centers?

A. I do.

Q. Let's mark that.

- - -

(Whereupon, Exhibit Blaivas-21, Abbott Paper, was marked for identification.)

- - -

BY MR. SNELL:

Q. This is one of the papers you cite to in your report?

A. Right.

Q. And the problem with a paper like this is it doesn't allow one to calculate the incidence or probability of a complication, correct?

A. Correct.

Well, I don't consider that to be a problem. But what you said is factually correct.

Q. This is, essentially, a series of patients who reported complications, and the paper reports on how they were treated, correct?

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A. Correct.

Q. In fact, I think if you turn back to the second-to-last page, it says, where they're talking about limitations, besides the fact it was retrospective, it says, Perhaps most importantly, there is no denominator for the total number of patients who underwent an SUI or POP procedure. Thus, we can make no comments about the rate at which such complications occur.

You agree with that?

A. I do.

Q. And this looks at not only the TVT sling mesh but the transvaginal mesh as well, for prolapse, correct?

A. Yes.

Q. And you acknowledge that the rates of potential complications with TVT are lower than that with the transvaginal prolapse mesh?

A. Yes.

Q. And what they state, if you look at the preceding page, just -- where

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it's got Table 4, it says, Additionally, those women with complications after sling-only procedure were treated more often with --

A. I'm sorry, where are you?

Q. Let me just show you, that way you can -- I don't want to lose time. I'm kind of reading right there.

A. Okay.

Q. Are you with me?

A. Where?

Q. Additionally, those women --

A. Yes.

Q. Tell me when you're there.

A. I'm there.

Q. Okay. This paper, they reported that women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical re-intervention, correct?

A. That's what it says, yes.

Q. And that's consistent with the literature, correct?

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A. No, I'm not -- it's consistent with the literature, but I don't agree -- again, I'm familiar with the methodology that came to those conclusions and the follow-up is simply too short to agree with their conclusion.

This is what the paper says. It's not data, it's their comment. And I would take issue with it.

Q. Well, their comment is based on data because they did look at how frequently the complication was treated with medical intervention as opposed to surgical intervention in the study, right?

A. Yes, but the follow-up was too short to have any meaningful -- to come to this conclusion.

There are other papers that I read recently, I'm sorry, I can't cite, and my own experiences, that many patients who have been treated medically are okay for six months or a year or two years and then go on to have

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complications. We've seen it over and over and over again.

So I just don't agree with that conclusion.

Q. Can you give me an accurate number as to the rate of the women who are treated within the first year and then have to have intervention later on down the road?

A. A sizable number. I can't give you the percent off the top of my head.

Q. Why would you cite to this paper, the Abbott paper, then, if you're disagreeing with the things they say about the TVT slings?

A. I didn't say I disagree with the things they said. I think the overall data -- there's lots of things in here that I think are important. It doesn't mean I have to agree with every statement.

Q. So some of their findings were actually inconsistent with your

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opinions, but you still cited to the paper, right?

MS. FITZPATRICK: Objection. Misstates the testimony.

THE WITNESS: I would say probably every paper has things you agree with and you disagree with. You take the -- you know, you take the good with the bad -- not is the good with the bad.

I mean, you -- there are some things that have good science to them. I mean, for example, I was looking for it and I can't quite cite this, but in this paper, there's data on what percentage of patients went back to their original doctor. And my recollection -- my recollection is that only about half of the patients -- I could be wrong, I could be off by 50 percent, but a significant percentage of the patients did not go back to the

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original doctor, probably never even knew this happened. So data like that is important.

And there were a number of things that I did think were important about -- about this patient. I mean, for example, the median number of surgeries per patient was one. But 21 percent of the patients required more surgery for the same thing. So one in -- so those kind of --

See, whenever there's a positive statement, something happened, you can be confident that it happened. But if -- if someone doesn't -- if someone doesn't report a complication, it doesn't mean there wasn't one.

But if someone reports it, it happened. And that's the way we get our information about complications.

BY MR. SNELL:

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Q. A couple of things I want to follow up on.

First, you mentioned that some of the patients didn't go back to their doctors?

A. Yes.

Q. We know these are tertiary care centers?

A. Yes.

Q. And you know -- do you know what percent of the patients were referred by their primary doctors to their tertiary care center for treatment of the mesh complications?

A. I think it's in the paper. But no, I don't know.

Q. Do you know what percentage of the tertiary centers actually communicated back with the referring doctors to tell them the outcomes and how patients were doing?

A. I don't. But that's exactly the kind of stuff that you want to know. Because that's -- let me leave it at

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that.

Q. Well, when you see a patient for a referral, or if you know who the primary treating gynecologist or urogynecologist is and you do a procedure, don't you write that doctor and say, here is what I did?

A. I ask the patient for their permission. I mean, because a lot of -- some of them don't want the doctor to know, God knows. But I need their permission to do that; unless the patient was referred to me by the doctor.

But I can tell you, I can -- I mean, the overwhelming majority of patients that I see are not referred by the operating doctor. And to a large extent, the operating doctor doesn't know about it.

And the reason I know is, because I usually ask -- I always ask the patient if it's okay to communicate with their primary -- with the doctor that did the surgery.

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Q. Are you aware of data to the contrary, that shows that more than 50 percent of patients go back to their primary doctors who did the implantation of the mesh for treatment?

A. I don't know -- I know a significant number don't. But I don't know -- I don't know the data well enough to answer that question.

Well, actually, I know that at least a third -- I read recently in one study --

Q. Go ahead. I'm listening.

A. I know in one study that I recently read, a third of the patients never notified their operating surgeon.

Q. A third, you said?

A. Yes.

Q. In this study, the average number of interventions was one, correct?

A. Yes.

Q. So more likely than not, once the patient has an intervention, according to this study, she will not

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need another one, correct?
A. No. That's what I was saying before. I mean, we've seen many patients that have had -- had an intervention and are okay for a couple of years and then need another one.
I mean, that's my practice. And I see that commonly.
Q. I understand. I understand that that can occur.
But I'm talking about probability.
A. We specifically looked -- was that a question? You did not ask a question yet, I'm sorry.
Q. My question was focused on probability.
I will give you that patients can go back for a second reoperation. I'm talking about probability and what the actual data showed.
In this study -- let me see, I think it's reported in here. For the

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sling cohort, less than half had to have a second surgery.
Is that consistent with your recollection of this study?
A. Yes. But the follow-up was -- the follow-up for all of these things is too short for there to be any meaningful conclusion about whether or not they needed another operation.
Q. Well, based on the data, though, it was more likely than not that one surgery would suffice in this study for the sling patients?
A. I just -- I just said what my opinion was.
Q. In the sling procedure, it said 23 percent had more than one surgery. So to that -- that, to you, does not mean -- 23 percent of the women who had these tertiary care center treatments had to have more than one surgery.
That does not mean, to you, that it's more likely than not that a

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patient will need just one surgery?
A. No, that's correct, it's not clear to me.
Q. Is it important to you to know whether or not a patient you're treating for mesh removal is involved in litigation?
A. No, not really.
Q. Have you evaluated the medical literature with regard to potential bias by financial gain to patients involved in litigation and how they report their symptoms to doctors?
MS. FITZPATRICK: Objection.
THE WITNESS: No.
BY MR. SNELL:
Q. Are you aware if there is literature, though, on that topic?
A. No.
Q. Haven't you written in the past that patients involved in litigation have a financial incentive to make claims?
MS. FITZPATRICK: Objection.

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THE WITNESS: I haven't written that, no.
BY MR. SNELL:
Q. You haven't?
In your opinion, does the TVT adequately treat stress urinary incontinence?
MS. FITZPATRICK: Objection.
THE WITNESS: In terms of efficacy, yes.
BY MR. SNELL:
Q. And in your opinion, I take it you believe that the pubovaginal sling also adequately treats stress incontinence?
A. Yes.
Q. Apparently, over lunch, or some time, you called someone to try to get information about why papers were left off of your review?
A. I did.
Q. Who did you call?
A. My previous -- actually, one of the authors of the paper, I think it

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was Matt Benedon. But he's a previous research coordinator.
Q. Where is he at now?
A. He's still in New York, but he doesn't work for me anymore.
Q. And what did you ask Matt?
A. Why those weren't there.
Q. What did he say?
A. That we used -- if the same author wrote a previous paper using the same cohort of patients, he only included the one with the latest -- our methodology was to only include the one the latest date.
So, for example, one of the papers we didn't -- I forget who the first author was, but the senior author was Nilsson, we did not include the five-year paper, we included the seventeen-year paper. There was a series of papers.
So there were three that -- that was one.
The Serati, or whatever that

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one was, the 2013 paper was -- the five-year follow-up was published later than the ten-year follow-up, because the ten-year follow-up was just TVT --
Q. Can I stop you right there?
A. Yes.
Q. First of all, the cohort of patients in Nilsson's study that's been reported out to 17 years, that I know you cited, is not the same cohort of people in the prospective randomized five-year control trial; you and I know that, right?
A. They're different -- no, they are different papers, right.
Q. They are different cohorts of patients, right?
A. Let me see the paper. Which one are you talking about?
Q. I'll take these one by one.
The first one you mentioned with Nilsson, that's the Laurikainen five-year RCT.
Where is your paper at?

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A. We may -- let me see the paper.
MS. FITZPATRICK: This is my copy of it. I don't know what number it is.
BY MR. SNELL:
Q. You said one with Nilsson. I think that's the one where Nilsson is on.
A. Give me one second.
Q. Can I look over your shoulder? I can't find mine in that big stack.
Yes, this is Nilsson, okay.
A. You're correct about that. But that's the explanation. They thought when the computer -- you know, the way we did it, it pulled it up as the same author, and they thought it was the same cohort.
Q. But it's clearly not, correct?
A. It's clearly not, correct.
Q. And it should have been

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included, correct?
A. Yes, it should have.
Q. And Serati, those are two different cohort of patients because the ten-year study was TVT patients and the five-year were TVT-O patients, correct?
A. And TVT. One of them had TVT and TOT, I thought.
Well, let me see the two papers, and we'll see.
MS. FITZPATRICK: I've only got one. I think we only have one marked, and I'm not sure what it is.
BY MR. SNELL:
Q. Do you have it in front of you there, Doctor?
A. I must.
MS. FITZPATRICK: Is it Number 12? Here. That's the only one we have. We don't have the second one, I don't think, the 2013.
THE WITNESS: I need to see

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the other one, the one that -- this is what year? I need to see the one that was printed -- what year is this?

This is 2012. We need to see the one from 2014. The same author had a paper in 2014.

MS. FITZPATRICK: 2013.

THE WITNESS: 2013.

BY MR. SNELL:

Q. But that was a group of TVT-O patients that were only analyzed at five years?

A. Can I just see it?

Q. I don't have it, but we have it on the computer here.

A. Let me see in the table -- hold on.

Let me just see in our table. I'll be able to tell just by looking in the table.

Q. I think the simple thing is this. I think you should be able to agree with me that a ten-year group of

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women who got TVT implanted is not the same group who had five-year follow-up after a TVT-O implanted?

A. Of course. But --

Q. In your paper, you cited to this five-year TVT-O paper, and I'll give you that, it's in there, but the ten-year TVT group was not in there?

A. Just let me check one thing.

That's correct. And that was -- that was just an error. But the error was because it was the same author with mesh slings. And our methodology said that if it was -- they mistakenly thought it was the same cohort.

Q. Clearly, it's important to capture ten-year TVT studies that are out there in the published literature and journals like European Urology, correct?

MS. FITZPATRICK: Objection.

THE WITNESS: Not to -- not in a safety consideration for synthetic sling study that is already -- there's plenty of data

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on. This doesn't change the conclusions one bit.

BY MR. SNELL:

Q. I thought you said that there is less long-term ten-year data on TVT?

A. Including this. I already went through the fact that the methodology to look at the kinds of complications that we saw is not sufficient. It didn't seek it out.

I mean, it didn't have a way -- I mean, again, I agree that 8 percent is a great loss to follow up. But the problem is, it's not so great -- it's great for efficacy. But it's not so great looking for complication that occurs in 1 or 2 percent of patients.

So if only one -- there's only one patient, one or two patients that had that complication, they were more likely to be in the loss-to-follow-up group according to -- or -- they were very likely to be, I

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couldn't say that they were more likely to be.

They are at least one-third more likely to be in that group because we know at least one-third of the patients don't go back to their original doctors.

So that an 8 percent loss to follow up, although extraordinarily commendable for an efficacy study, is not so commendable to look for something that happens 1 or 2 percent of the time.

Q. The problem with what you just said, though, Doctor, is when you said we know a third of the patients don't go back to their doctors, we know that in Serati, 92 percent of them went back to their doctors, right?

MS. FITZPATRICK: Objection.

THE WITNESS: That's right.

But 8 percent did not.

BY MR. SNELL:

Q. But 8 percent and a third is a big difference, isn't it?

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MS. FITZPATRICK: Objection.
THE WITNESS: Well, no, no. I actually stand by what I said. I don't think I need to say it again.
BY MR. SNELL:
Q. So in Serati's paper, where only 8 percent didn't go back to the doctor, why are you telling me that we know a third of patients don't go back to their doctor?
MS. FITZPATRICK: Objection. Mischaracterizes his testimony.
THE WITNESS: The reason I said that is there's a chance that the -- let's say these -- I forget the numbers now, but these were, like, 60 patients or 70 patients.
So 60 patients, if one -- we would not expect there to be more than one, say, erosion out of that. That would be -- you know, that would, or urethral obstruction that required -- say

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requiring surgery would be 1 or 2 percent. Okay.
So there only -- in that 8 percent, the one patient could have been the one patient who had the complication, and that one patient, it would be more likely that that person would be in the loss-to-follow-up group than in the not loss-to-follow-up group.
BY MR. SNELL:
Q. How is it that you can say that that one patient is more likely in the loss-to-follow-up group than the 92 percent of the patients who did return?
MS. FITZPATRICK: Objection.
THE WITNESS: I already explained my rationale for that.
BY MR. SNELL:
Q. I don't understand it.
It would seem to me that sheer statistical 92 percent probability that they would come back?
MS. FITZPATRICK: Objection.

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BY MR. SNELL:
Q. I'm really trying to understand your methodology and your statement there.
MS. FITZPATRICK: Objection to the form of the question.
THE WITNESS: I'll try to say it again.
I didn't say they're more likely to be in that group. I didn't say that they are more likely to be in that group. It's just that I think that -- maybe I did say that. If I did, I misspoke.
I said there's a chance that they could be in the group. And since the complications we're talking about are so uncommon, okay, I don't think it's fair to say that if a complication didn't occur in the 92 percent of the patients that were followed up, that, therefore, it never

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occurred. That's all I'm saying.
BY MR. SNELL:
Q. Okay. We can agree that in Serati's paper, where 92 percent of the patients did come back and they didn't report any de novo dyspareunia and they did not see any exposure, that's actually a good thing for those patients who came back and were able to be evaluated?
A. I'm going to split it between the dyspareunia and the erosion.
All the patients were examined, so I'll give you that.
But the dyspareunia, if you don't ask about it and you don't know if the patient is sexually active, you can't make a comment about dyspareunia, in my judgment. If they say they have dyspareunia, you can make a comment. If you did not say specifically, do you have sex and does it hurt, I don't think you can say -- you can make a comment.
Q. But when the authors report there was no de novo dyspareunia, that

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means they asked about it, they assessed it, right?
A. If that were the case, it would be in the methods. And if it wasn't -- if they asked about it and did not put it in the methods, then it's their fault for not putting it in the methods. And if they didn't ask about it, then they can't conclude it.
And I don't even like talking about this because I think it's very good paper. I don't mean to malign the authors at all. This is an excellent paper, but just not with respect -- they did the best they could with this stuff. But it's not good enough to satisfy me that if the patients don't complain of pain, they don't have it.
I haven't -- I made my statement.
Q. Regardless, that's a paper that should have been in your review, right?
A. Yes.

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Q. And you were about to -- were you about to give me some justification for why the other paper didn't show up in there?
A. Which one was that?
Q. Heinonen, 10.5 years, follow-up, no long --
A. Which one?
Q. Heinonen, 10.5 years --
A. I need to see it.
MS. FITZPATRICK: This one.
BY MR. SNELL:
Q. No late tissue reaction exposure, where they did vaginal examinations with speculum?
A. This just missed the table, it's in the paper. This is referenced, it's part of our data. We just -- it didn't get in the table.
Q. In your paper, you reported there were only 11.
That one obviously should have been in there as well?
A. Yeah. But we did use it as

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data and we did use it for calculations. It just didn't make -- it just didn't get in that table.
Q. So there is much more five year long-term data in the literature than what you put in that table, correct?
A. Well, there are three.
Q. Three that I showed you today?
A. Yes.
Q. There could be 12 more?
MS. FITZPATRICK: Objection.
THE WITNESS: I don't know.
But if there are, let's not discuss them today.
BY MR. SNELL:
Q. Is part of your methodology based on case series?
A. Yes.
Q. Do you give more weight to case series than randomized control trials or systematic reviews?
A. I give weight to anything that documents a complication. I don't

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give weight to someone that doesn't comment on -- you know, on complications.
So most of the studies, many -- I would say -- I could say that most of the studies don't even have anything in their methodology to accrue complications, other than -- than patient reported.
So if the patient says -- said that it hurt, something hurts, they would accept it. But they don't -- if they don't prompt for it, they don't check for it, I don't give that any credence at all.
Q. Nilsson, 17-year paper?
A. Yes.
Q. Are you critical of the loss to follow up in that paper as being something outside the norm for a 17-year data set or is that within the norm of what you would expect at 17 years?
A. Again, the loss to follow up, I think, was acceptable for that period of time. But some of the stuff

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they could have -- you know, loss to follow up Alzheimer's disease, that was one of the categories. That does not mean that the patient didn't have a mesh erosion, it did not mean they didn't have dyspareunia; it just means they have Alzheimer's disease.

And the patients -- of course the patients that died. But I would have wanted to see them -- and they did not prompt for the kinds of complications that we're talking about.

Q. Did the majority of the mesh complications occur in the first year?

A. In that paper.

Q. No, no. In general?

A. In general, yes. I would say the majority of reported complications occurred in the first year.

Q. Do you know who -- you know Stuart Stanton?

A. Sure.

Q. He was one of the surgeons who was highly involved in bringing about

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the Burch or at least reintroducing it, correct?

A. Yes. Wait a minute. Sorry. I'm not sure I know what you're talking about with the Burch.

Q. He's over in England, London?

A. I know exactly who he is. But, I mean, what was -- I didn't get your comment about the Burch.

Q. Let me withdraw my comment.

You know who Stuart Stanton is?

A. Yes.

Q. A surgeon in London who has published on the Burch colposuspension?

A. Yes.

Q. In a study where he looked at the Burch ten to twenty-year follow-up, the loss to follow up was about 68 percent.

Is that an acceptable level of loss to follow up, in your opinion, for a study of ten to twenty years'

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duration?

A. I mean, it's understandable. I mean, when you say "acceptable," there's a difference between what's practical and what's scientific -- it's not scientifically acceptable. But practically, of course, it's acceptable.

Q. When you say "practically it's acceptable," you mean stuff happens?

A. It's the best you can do, yeah.

MR. SNELL: Let's mark that.

- - -

(Whereupon, Exhibit Blaivas-22, Stress Urinary Incontinence AUA Monograph, was marked for identification.)

- - -

BY MR. SNELL:

Q. Doctor, I've given you a stress urinary incontinence AUA monograph.

You're familiar with this document?

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A. I am.

Q. Do you actually use a stress urinary incontinence monograph with your patients who have incontinence?

A. I do not. You mean -- no, I don't.

Q. If you look at Page 10, where they're talking about surgical management, you see mesh and pelvic floor surgery on the right?

A. Yes.

Q. Where they talk about the -- they refer to the AUA's October 2013 position statement on the use of mesh, correct?

A. Yes, they do.

Q. And a little further down where they're talking about complications, the AUA, they report that prolonged pain occurs in 1 percent?

A. Yes.

Q. You agree with that?

A. No.

Sorry for laughing.

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Q. Well, that's very similar to the 1.4 percent you reported in your paper, correct, for retropubic slings, at least?
A. That's based on the flawed literature we discussed. We said that we believe it's more like 4 percent, based on the analysis that I described before.
Q. But I'm only focused on the retropubic TVT, not lumping in transobturator slings.
That 1 percent reported in this AUA monograph is consistent with the 1.4 percent you reported specifically for the TVT and retropubic slings in your paper, right?
A. Yes.
Q. And the vaginal exposure, 1 to 2 percent, is also consistent with what was reported with regard to the retropubic TVT in your paper?
A. Yes.
Q. And the erosion into the urinary tract, less than .01 percent,

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that's consistent with what you found?
A. No, it's not. We found about, I think it was .4 percent, just for the record, which is --
Q. .4 percent for erosion in the bladder?
A. This says bladder or urethra.
Q. Erosion into the urethra, you would agree, is less than .01 percent?
A. Probably around that. It's uncommon.
- - -
(Whereupon, Exhibit Blaivas-23, American Urology Association Position Paper, was marked for identification.)
- - -
BY MR. SNELL:
Q. Exhibit 23, this is the AUA position statement --
A. Okay.
Q. -- on the use of vaginal

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mesh. And this is the October 2013 revised statement.
Do you see that?
A. Yes, I do.
Q. AUA says, Extensive data exists to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI with minimal morbidity compared to alternative surgeries.
Do you see that?
A. I do.
Q. You agree with that part of the position statement?
A. Do I agree what?
Q. You agree with that part of the position statement from the AUA?
A. I agree it says that. But, no, I don't agree with that. Again, I -- no, I don't agree with that.
Q. Advantages include shorter operative time, anesthetic need, reduced surgical pain, reduced hospitalization and reduced voiding dysfunction.

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I think we covered most of those before, except we didn't get into reduced surgical pain.
You would agree there is reduced surgical pain with the TVT compared to --
A. You mean perioperative? Yes.
Q. Which is -- it's consistent with having to strip off the woman's tissue?
A. Sure.
Q. That can be very painful, correct?
A. I mean, it's like -- I would say it's less so than most operations, because we don't go into the abdominal cavity.
Q. And that would be a benefit --
MR. SNELL: I'm sorry?
MS. FITZPATRICK: It's about 5:50, I want you to know.
MR. SNELL: You have a hard

stop?

- - -

(Whereupon, a discussion off the record occurred.)

- - -

MR. SNELL: I will put on objection on the record, because I would have liked to complete this deposition today. I will ask that there be obviously no communication between you and the witness, if we resume. And I'm not even sure if I'm willing to resume.

MS. FITZPATRICK: Well, I'm going to have 15 minutes, so if you don't want to come back for it, we'll do a 15-minute follow-up by phone.

MR. SNELL: Those things being said, you have a safe trip to your meeting, Doctor.

THE WITNESS: Okay.

- - -

(Whereupon, Exhibit Blaivas-24, Expert Report of J. Blaivas, was marked for identification.)

- - -

(Parties agreed to mark the expert report as 24.)

- - -

(Whereupon, the deposition concluded at 5:49 p.m.)

- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

Amanda Maslynsky-Miller
Certified Realtime Reporter
Dated: September 21, 2015

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 349, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

JERRY BLAIVAS, M.D., DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC.,	:Master File No.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:2:12-MD-0237 : :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE
Mullins, et al. V. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. V. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. V. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. V. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. V. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. V. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. V. Ethicon, Inc., et al.	2:13-cv-11022
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. V. Ethicon, Inc., et al.	2:13-cv-14799
Vanbuskirk, et al. V. Ethicon, Inc., et al.	2:13-cv-16183

SEPTEMBER 24, 2015
CONTINUED DEPOSITION OF JERRY G. BLAIVAS, M.D.

CAPTION CONTINUED:
Mullens, et al. V. Ethicon, Inc., et al. 2:13-cv-16564
Shears, et al. V. Ethicon, Inc., et al. 2:13-cv-17012
Javins, et al. V. Ethicon, Inc., et al. 2:13-cv-18479
Barr, et al. V. Ethicon, Inc., et al. 2:13-cv-22606
Lambert v. Ethicon, Inc., et al. 2:13-cv-24393
Cook v. Ethicon, Inc. 2:13-cv-29260
Stevens v. Ethicon, Inc., et al. 2:13-cv-29918
Harmon v. Ethicon, Inc. 2:13-cv-31818
Snodgrass v. Ethicon, Inc., et al. 2:13-cv-31881
Miller v. Ethicon, Inc. 2:13-cv-32627
Matney, et al. V. Ethicon, Inc., et al. 2:14-cv-09195
Jones, et al. V. Ethicon, Inc., et al. 2:14-cv-09517
Humbert v. Ethicon, Inc., et al. 2:14-cv-10640
Gillum, et al. V. Ethicon, Inc., et al. 2:14-cv-12756
Whisner, et al. V. Ethicon, Inc., et al. 2:14-cv-13023
Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664
Schepleng v. Ethicon, Inc., et al. 2:14-cv-16061
Tyler, et al. V. Ethicon, Inc., et al. 2:14-cv-19110
Kelly, et al. V. Ethicon, Inc., et al. 2:14-cv-22079
Lundell v. Ethicon, Inc., et al. 2:14-cv-24911
Cheshire, et al. V. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al., V. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al., V. Ethicon, Inc., et al. 2:14-cv-29624

Continued transcript oF JERRY G. BLAIVAS, M.D., called for Oral Examination in the above-captioned matter, said deposition taken by and before SILVIA P. WAGE, a Certified Shorthand Reporter, Certified Realtime Reporter, Registered Professional Reporter, and Notary Public for the States of New Jersey, New York, Pennsylvania and Delaware, at the offices of URO CENTER, 445 East 77th Street, New York, New York, on Thursday, September 24, 2015, commencing at 2:48 p.m.

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None

Motion to Strike

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JERRY G. BLAIVAS, M.D.,
Uro Center, 445 East 77th Street, New York, New York, after having been duly sworn, was examined and testified as follows:

CONTINUED EXAMINATION BY MR. SNELL:

Q. Dr. Blaivas, I'm going to be brief. I'm Burt Snell. We're just picking up on your deposition.

Have you done any work since the time of your deposition I took from you on Friday, looking at any materials, talked to Plaintiffs' counsel?

A. I haven't talked to Plaintiffs' counsel. I did some work -- I mean, I did some more reading of stuff that was already -- I just reread some of the stuff that was already on the reliance list.

Q. Let me ask you this.

A. Excuse me just one second. I'm just trying to turn my phone off and I can't seem to do it while we're talking.

MR. SNELL: Let's go off the record.

(There is a discussion off the record.)

MR. SNELL: Okay. Back on.

Q. I saw from your website and I think

your CV that you're involved with some companies.

A. Yes.

Q. What types of development or products are you working on?

A. My overwhelming effort is a company that I founded called SomeTelligence and we're working on -- we're working on a new method of facilitating communications between doctors and patients that allows most of the history to be obtained for the patient and doctor by the patient on the cell phone and then that gets translated into an outcome score that serves as the first step in diagnosis and then it's useful for following patients for treatment and clinical research.

Q. Have you invented anything?

A. Yeah. Yes.

Q. What?

A. I invented a device for measuring urethral mobility -- simultaneously measuring urethral mobility and leak point pressure as an objective measure of the severity of incontinence --

Q. Did you sell --

A. -- stress incontinence.

Q. Did you sell that device to anyone?

A. Yeah. It was actually -- it was produced for a short time by a company called -- I'm trying to remember the name. I'm drawing a blank on the name of the company. But they were then subsequently sold by AMS and they never did anything with it. It just sort of got buried.

Influence was the company. Influence was the name of the company.

Q. Were you paid anything for your invention?

A. I had stock options, yeah.

Q. Did you find that reasonable, that you were paid for your invention via stock options?

A. Sure.

Q. Would you describe yourself as entrepreneurial?

A. Not really. I'm not motivated by business and financial things, you know. So I don't consider myself "entrepreneurial."

Q. Let me pick up partly where we left off. We were talking about the AUA guidelines and the monograph and then the updated position statement and we had marked that.

You're aware that there are position

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statements and guidelines by AUG, SUFU, IUGA and other entities involved in women's public health?
A. I am.
Q. And some of those guidelines speak to the utility of the TVT retropubic device?
A. I'm aware of that, yes.
Q. Is it that you disagree at all with those statements and guidelines with regard to TVT's utility?
MS. FITZPATRICK: Objection.
A. I don't understand what you mean by "utility."
Q. The usefulness of the device.
MS. FITZPATRICK: Objection.
A. I disagree with the safety aspect of it. I don't disagree with the efficacy aspect.
Q. Okay. And you remember at the last deposition I showed you some longer-term TVT studies that hadn't been considered by you in your review?
A. Yes. But it turns out that some of them had been. They just weren't included in the table but, yes.
MR. SNELL: Give me some exhibits.
Q. I want to show you some others. I

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want to do these quickly because I don't have a lot of time.
(Deposition Exhibit Blaivas 25, Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: Monofilament vs. Multifilament polypropylene tape authored by Jens Christian Prien-Larsen and Lars Hemmingsen, was marked for identification.)
Q. First one, Exhibit 25, Doctor, the 6.5-year study in the International Urogynecology Journal.
You're familiar with that journal, right?
A. I am.
Q. This study by Prien-Larsen was not included in your table in your review.
Have you reviewed this paper?
A. Study by whom?
Q. Prien-Larsen. I may not be pronouncing the name right.
A. Oh, okay.
MS. FITZPATRICK: Do we have a copy of his "Nature" article, too, so he can look at it?
MR. SNELL: Do you have a copy of it?
MS. FITZPATRICK: I've got an

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electronic copy of it.
THE WITNESS: I, actually, think there is one on my desk.
MS. FITZPATRICK: Maybe it's conveniently --
MR. SNELL: Well, let's take a break and go off the record.
(Recess taken 2:53 to 2:54 p.m.)
Q. So, Dr. Blaivas, I've given you my copy of your review article that we had previously marked as Exhibit 4, correct?
A. Correct.
Q. And, if you look at Table 1, it has the five-year plus studies.
This paper that I've handed you by Prien-Larsen was not included, correct?
A. It wasn't included in the table. But I don't know if it was included in our analysis because this table related to effectiveness studies and we may have had different criteria for including those in the table.
Q. Okay. And what you'll see in this paper is they have looked at not only effectiveness but safety of TVT compared to IVS in this paper,

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right?
A. Let me...
Q. If you look in the result section.
A. No, I want to look at something else first in the methods section.
MR. SNELL: Then go off the record.
(Recess taken 2:55 to 2:56 p.m.)
MR. SNELL: Back on the record.
Q. This study we're looking at by Prien-Larsen, L-a-r-s-e-n, looked at not only efficacy but also safety, correct?
A. I don't see anything about safety.
Q. Okay.
A. There's one -- go on.
Q. I'll show you.
So, for efficacy, they compared TVT to IVS and, for example, at the last follow-up there was 94 percent objective cure with TVT and 80 percent with IVS with TVT being statistically significantly better, correct?
A. If that's what it says. I don't --
Q. Can I direct your attention to the front, just so you and I are on the same page?
A. Uh-huh.

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Q. I would not misrepresent some data to you.
A. No.
Q. Is that okay?
A. Yeah, I agree.
Q. A P-value of less than .03 is statistically significant, correct?
A. Yes.
Q. Okay. And there was a significant decline in subjective cure that was seen in the IVS cohort, correct?
A. Correct.
Q. Vaginal erosions were tracked in the study as well, right?
A. Yes. Well, it -- it wasn't tracked. It says that it was defined as -- it doesn't actually say how they determined that.
Q. You see they say that vaginal erosions were found in 11.8 percent of women in the IVS group and none in the TVT group, correct?
A. Yes.
Q. And under the results follow-up, you'll see the median follow-up in this study was 78 months, correct?

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A. Let me just see. I just want to check one thing out.
Yeah, I'm not finding the numbers lost to follow-up.
MR. SNELL: [MOTION] Move to strike.
Q. You see my question was, Doctor -- and I have very limited time -- the median length of follow-up in the TVT group was 78 months, correct?
A. Yes.
Q. Alright. And you'll see, actually, all of Page 706, they have a whole section on the treatment of these vaginal erosions.
A. Yes.
Q. And that flows all the way over to the next page, Table 5, where they identify all the different presenting symptoms in women with vaginal erosions, correct?
A. Yes.
Q. Including how treatment was necessary or not in the women who had the vaginal erosions, correct?
A. Yes.
Q. And, just to reiterate, and all of these patients with erosions were in the IVS group,

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correct?
A. Yes.
Q. And the IVS mesh is not a Type 1 macroporous monofilament polypropylene mesh, correct?
A. The which?
Q. The IVS mesh is not a Type 1 monofilament --
A. No, it's not.
(There is a discussion off the record.)
A. Excuse me. It's not. It's not.
Q. Just so we have a clear record now, the IVS where there was over an 11 percent rate of vaginal exposure seen is not a Type 1 macroporous monofilament polypropylene mesh like TVT retropubic, correct?
A. Correct.
Q. Alright. And do you have any idea why this paper wasn't cited in your review?
MS. FITZPATRICK: Objection.
A. I assume it was likely an exclusion criteria based on our very detailed methodology. I don't know.
Q. You don't know that as you sit here

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today?
A. No.
(Deposition Exhibit Blaivas 26, Long-term Results of the Tension-free Vaginal Tape Procedure in an Unselected Group: A 7-year Follow-up Study authored by Andreas Reich, Frauke Kohorst, Rolf Krelenberg and Felix Flock, was marked for identification.)
Q. Exhibit 26, you see this is long-term results of the TVT procedure in an unselected group of patients, seven-year follow-up, correct?
A. Let me look at it. I mean, I'm seeing this for the first time.
Q. Fair enough. Let me ask you this. This is, actually, published in the Journal of Urology, correct?
A. Yes.
Q. That's a journal you get, right?
A. Yes, I get it.
Q. Is that the journal to my left here on the bookcase?
A. It is.
Q. Okay. Fair enough.
MR. SNELL: Go off the record.

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Q. Can you look at it.
A. Okay.
(There is a discussion off the record.)
Q. So this was a study where the median follow-up time was 102 months, correct?
A. Yes.
Q. So that's what about nine years?
A. Uh-huh.
Q. Is that a yes?
A. Yes.
Q. And they looked at cure rates as well as complications, correct?
A. I'll have to look at that and see.
Q. In the results section, it says the objective cure rate was 89.8 percent and then they go on and talk about subjective cures and improvements. Do you see that?
A. Yes.
Q. This study, also, stated no late onset ever.
So events of the surgery were found in the results section, correct?
A. Yes.
Q. And, if we look at your Table 1, this

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long-term TVT study was not included either, correct?
MS. FITZPATRICK: Objection. This is misrepresenting completely what's in this article.
A. It's --
MS. FITZPATRICK: I'm objecting to that question.
MR. SNELL: That's fine.
MS. FITZPATRICK: Because --
MR. SNELL: No, no.
[MOTION] Move to strike attorney comment. You have a form.
MS. FITZPATRICK: I'm not going to move to strike it. This is complete misrepresentation.
MR. SNELL: [MOTION] Move to strike.
MS. FITZPATRICK: I'm going to put my objection on the record.
MR. SNELL: That's fine. Then just say your objection, form. You're wasting my time. I have limited time. Quit burning my time with your talking.
MS. FITZPATRICK: This is a misrepresentation.

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MR. SNELL: Allot her time to her. Go ahead.
MS. FITZPATRICK: This is a misrepresentation by Mr. Snell of this article. And, quite frankly, at this point, it's an intentional misrepresentation.
This article is cited for the safety propositions that Dr. Blaivas has in this article. The fact that it is not in Table 1 should be the question --
MR. SNELL: Move to strike --
MS. FITZPATRICK: -- not that it is not cited in the article.
MR. SNELL: [MOTION] move to strike attorney testimony.
MS. FITZPATRICK: Objection to the motion to strike.
Q. Dr. Blaivas --
MS. FITZPATRICK: And objection to attorney misrepresentation of something that I hope, certainly, doesn't see the light of day in court pleadings.
MR. SNELL: You know, if you want to get in the chair, get in the chair. I can depose

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you.
MS. FITZPATRICK: Sure. I'm happy, go right ahead.
Q. Dr. Blaivas --
MS. FITZPATRICK: -- after me.
MR. SNELL: I'm sure.
Q. So back to what I read to you, right. The results say, no late onset adverse effects of the surgery were found, correct?
A. Yes, that's what it says.
Q. This study was not referenced in your Table 1 of long-term TVT studies, correct?
MS. FITZPATRICK: Objection. Table 1 is effectiveness and what you're referring to is safety. Stop misrepresenting, Burt.
MR. SNELL: Did you just hear me say what the objective cure rate? This does --
Q. Doctor --
MS. FITZPATRICK: Did you just -- can you read back his question?
Q. Doctor, look, let's make sure that we're one same page.
MR. SNELL: You're wasting my time.
MS. FITZPATRICK: Burt, you're

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misrepresenting.
Q. Doctor, this is -- I withdraw my question.
Did this study assess efficacy of the TVT?
A. It is --
MS. FITZPATRICK: Objection.
A. It is efficacy, yes.
Q. And this study is not in Table 1 of your review, correct?
A. That is correct.
Q. Fair enough.
Now, if we look at -- you know what, can I see...
A. Are you looking for this?
Q. I just want to make sure I didn't say something.
So it's not in Table 1, correct?
A. Correct.
Q. And this study published in Urology -- is that a well-regarded journal by you?
A. It is.
Q. (Continuing.) Found no tape exposures or tape extrusions, correct?
A. That's what they said in the article,

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right.
Q. They also said that at the point of follow-up 29 women were sexually active, correct?
A. I'm sorry?
Q. At the state of follow-up, 29 women were sexually active? I'm right about --
A. Out of 108, yes.
Q. Yes. And no woman suffered under dyspareunia, correct?
A. It says that, but there is no methods -- there's no method to say how they determined that.
Q. And they also state no further late adverse effects such as chronic pain or recurrent lower urinary tract infection were found, correct?
A. Correct. But, again, that's not in the method. So I don't know how they can conclude it in their results.
Q. Does the Journal of Urology have a poor peer review process?
A. I think so. I think they -- yes, I think it does. This isn't the Journal of Urology. This is --
Q. Urology.

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A. -- Urology. I think -- I wouldn't want to single out the Journal of Urology. I think that when it comes to results, I think -- excuse me. When it is comes to complications, I think they're all poor.
Q. But you don't have any firsthand knowledge about what the authors did with regard to their assessment of dyspareunia or chronic pain?
A. Well, of course not. That's supposed to be in the methods section.
Q. I'm just saying.
So you don't have firsthand personal knowledge that these authors did not assess dyspareunia or chronic pain?
MS. FITZPATRICK: Objection.
A. That's right. It did not.
MR. SNELL: Next study is Lispis. Let's mark this as Exhibit 27.
(Deposition Exhibit Blaivas 27, Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: Efficacy at 5- and 7-year follow-up by A. Lispis, P. Baskas and G. Creatsas, was marked for identification.)

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Q. And looking back at the paper that we just referenced, Doctor, by Reich in Urology, do you have any idea why that was not included in Table 1?
A. I already said, we had inclusion and exclusion criteria, No. 1. No. 2, because it's not in the table doesn't mean it isn't in our references, in the nearly 400 references. So I have to cross-check to see whether it was included or not.
Q. As you sit here, you don't know why it wasn't included in Table 1?
A. I don't know if it wasn't included. That's what I said.
Q. Okay. What exhibit is that, Doc, 20?
A. Twenty-seven.
Q. Twenty-seven.
Exhibit 27 is a paper with seven-year follow-up in TVT by Dr. Lipis, L-i-p-i-s, and some others. And I just want to check and we can check together.
A. Yes.
(There is a discussion off the record.)
Q. And this was a paper that wasn't referenced in Table 1 of your review, correct?

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A. That's correct.
Q. Okay. And if we look at this paper -- let me ask you.
As you sit here, do you know why this paper was not referenced?
A. No. The same answer I gave for the other ones. We'd have to see if it met our inclusion and/or exclusion criteria.
Q. It did report on efficacy, right, if we look at Table 3, they report on both objective and subjective cures?
A. I'm sorry? I didn't understand the question.
Q. This paper, seven-year follow-up by Dr. Lipis and others, did assess efficacy of TVT --
A. Yes.
Q. -- in both five and seven years, correct?
A. Correct.
Q. And those data are in Tables 2 and 3, correct?
A. Yes, yes.
Q. Three being the seven years.
A. Yes.

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Q. And they, also, reported on complications as well, correct? If you look at the bottom of Page 1510, right column, they said that they had one case of the TVT tape erosion.
A. Again, I'd have to look at the methods to see if there's any method that -- I'm looking at it quickly -- for detecting it. And I don't see anything. I mean, I looked quickly, but I don't see any methodology to allow us to understand how they came to the conclusion who had a complication and who didn't.
Q. Well, when you do a vaginal exam, if you see a mesh exposure, you document it, right?
MS. FITZPATRICK: Objection.
A. If the patient -- yes, you do. But if the patient doesn't complain of any symptoms, you may do a very cursory exam or they can have many other complications that wouldn't be apparent on examination.
Q. Well, whatever methodology they use, they reported that they found an exposure and they actually treat it by incising the sling, correct?
A. Correct.
Q. And you're not saying that -- are you

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saying that that didn't occur?
A. No, I'm not saying it didn't occur. What I am saying is that in order to determine whether or not someone has a complication or whether all patients have a complication, you have to have a methodology like asking a whole bunch of questions, for example, about complications or giving them a questionnaire to fill out and only by doing that can you determine what the denominator is.
Q. And you don't know the methodology by which they did that in this case?
A. No. I would expect to see it in the paper.
Q. And they note that the rest of the patients had no evidence of tape erosion at the seven-year follow-up, correct?
A. Right.
Q. So these are -- this is three different studies we've looked at that weren't included in Table 1, correct, of your review?
A. They weren't included in Table 1 for efficacy, correct.
Q. You don't know why they weren't included, right?

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A. I would have to check the inclusion and exclusion criteria to see why they...
Q. And -- fair enough.
And none of these three additional studies reported late-term dyspareunia or tape exposure or erosion, correct?
A. Nor did they have methodology to assess it, except for a pelvic exam.
MR. SNELL: [MOTION] Move to strike.
Q. Can you answer my question?
MS. FITZPATRICK: Objection, the answer will stand. It's been asked and answered. Let's move on.
MR. SNELL: No.
Q. I want a yes or no --
MS. FITZPATRICK: No.
Q. -- then you can put your caveats in.
MS. FITZPATRICK: You answer whatever way you have to to give a full and complete answer. It doesn't have to be a yes or no.
THE WITNESS: I believe I did.
MR. SNELL: Read it back.
THE WITNESS: What's my answer?
MR. SNELL: Read it back.

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(Whereupon, the answer is read back as follows:
"Answer: Nor did they have methodology to assess it, except for a pelvic exam.")
A. And that's my answer. If you want me to say, no, I can say, no, nor --
Q. That's fine.
A. -- did any of them have methodology to answer the question.
Q. Yes, that's what I'm looking for, a responsive answer. And I'm more than happy to --
MS. FITZPATRICK: Objection to the attorney comment.
Q. I'm more than happy for you to give your caveat or whatever else. I'm not trying to stop you from doing that.
This judge in this litigation has said a witness will be responsive, but they can give their caveat or whatever. So I'm giving you that. I'd just like an answer. And I thank you.
MS. FITZPATRICK: You can answer any way you need to answer.
MR. SNELL: Pass the witness.
EXAMINATION BY MS. FITZPATRICK:

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Q. Dr. Blaivas, I just have a few questions for you now.
You testified that you're not a pathologist, correct?
A. Correct.
Q. Now, does that mean that you don't perform any pathology analysis in human tissue, correct?
MR. SNELL: Objection, leading.
A. I don't perform them, no, correct.
Q. Do you as a physician order pathology review by pathologists on samples that you have removed from patients?
A. I do.
Q. And you just don't personally perform the analysis on explanted transvaginal mesh, correct?
A. To a certain -- part of it I, actually, do because I exam it and part of the pathologic exam is to touch and feel it after it comes out. And I do do that in every case and I communicate that to the pathologist. But I'm sad to say they don't always keep -- include it in their report.

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Q. Okay. And, as part of your education and training and experience as a urologic surgeon, you send specimens to pathology for review, correct?
A. I do.
Q. And that includes explanted transvaginal mesh that you remove from your patients, correct?
A. Yes.
Q. And that's a removal that is done by you as a physician and not in connection with litigation, correct?
MR. SNELL: Objection, lacks foundation and is leading.
Go ahead.
A. Yes.
Q. And you regularly rely on pathology reports generated by pathologists in connection with your work as a urologist, correct?
A. I do.
Q. Okay. Do you have training and experience as a urologic surgeon relating to pathology -- strike that.
Do you have training and experience as a urologic surgeon relating pathology reports to

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clinical complications in women?
MR. SNELL: Objection, vague.
Go ahead.
A. I do.
Q. And have you relied on this experience in connection with your report in this case?
MR. SNELL: Objection, leading, lacks foundation, lacks methodology.
Go ahead.
A. I do.
Q. Have you relied --
MS. FITZPATRICK: Burt, go back to law school if you think that's leading.
Q. Have you relied on your experience in this regard in connection with your report in this case, Dr. Blaivas?
MR. SNELL: Same objections.
A. I do but with an explanation. I very frequently, in fact, almost routinely question the pathologist about the pathology reports because they routinely don't do all of the things that I think should be done as part. So I often, you know, discuss it with them and sometimes ask them to not

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-- well, to give me a revised report based on things that they didn't include in the original report. I don't ask them to change, you know, their findings. But not infrequently -- for example, many times they don't even look at the tissue under the microscope. And so the report will just come back, you know, tan tissue without any microscopic diagnosis. So, when that happens, I'll ask them if they would look at it under the microscope and render their opinion about that.

Q. Okay. In addition to your experience in treating patients and reviewing their pathology reports, as you've just described, are you also familiar with medical and scientific literature concerning pathology examination of explanted transvaginal meshes?

A. Yes.

MR. SNELL: Leading.

Go ahead.

Q. And do you -- have you authored any peer review articles that deal with pathology of explanted transvaginal meshes?

A. I have.

Q. And when was that published?

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A. Well, it's the nature of the review article that we alluded to before in 2015. And we had an abstract and it was published -- myself and Dr. Yacoub had an abstract published in 2014 in the ICS, in Your Urology or in Uro Dynamics that we have not completed the manuscript on that yet.

Q. And have you also authored peer review articles that deal with the correlation between clinical complications and pathology review of explanted transvaginal meshes?

MR. SNELL: Objection, leading.

A. Yes.

Q. And are those the same articles that you just mentioned?

A. They are.

Q. Okay. Do you need to be a pathologist or a pathology expert to offer the opinions that you have offered in this case?

A. Of --

MR. SNELL: Objection, lacks foundation -- hold on -- lacks foundation, leading.

A. Of course not.

Q. Why not?

MR. SNELL: Same objections.

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A. Because it's part of what I do.

MS. FITZPATRICK: Okay. We're going to take the objections and they're going to count towards whatever time he has left. So, to the extent that someone is going to object to why not as a leading question, that is nothing more than harassing and a complete abuse of the system.

MR. SNELL: No, it's not. My original objection stood. You asked a follow-up one and it's only natural that I re-assert it.

MS. FITZPATRICK: No, it's not.

MR. SNELL: Go ahead.

A. I have forgotten the question.

Q. Why don't you have to be a pathologist or pathology expert to offer the opinions that you have offered in this case?

MR. SNELL: Same objection, foundation also.

A. Because my opinions are based on -- they're simply based on pathology and the patient's clinical course. I mean, I don't know how to explain it in more detail than that.

Q. And is that something you routinely do as a physician in treatment of women who had

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pelvic mesh implants?

A. Absolutely.

Q. Now, you were also asked whether you were an infectious disease specialist. Do you recall that?

A. I do.

Q. Do you believe that you need to be an infectious disease specialist to offer the opinions that you have offered in this case?

MR. SNELL: Objection.

A. No, I do not.

Q. Why not?

A. Because infectious disease specialists for practical purpose is never or almost never see the kind of infections that we see related to this. I see much more myself than any single infectious disease doctor would see.

Q. And do you regularly work --

MR. SNELL: I'm going to move --

Q. -- to develop --

(There is a discussion off the record.)

Q. Do you regularly work with women who have developed infections secondary to the presence of mesh, transvaginal polypropylene mesh, in this

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office?
A. I --
MR. SNELL: Hold on.
[MOTION] Objection. I'm going to move to strike the last answer as totally speculative.
Go ahead.
Q. And have you treated those women?
A. I'm sorry. I forgot the question now, again.
Q. That's exactly what he's trying to do, Dr. Blaivas. So just pay attention to me and not to Mr. Snell, who is trying to throw you off your game here.
In fact, in your training, education and experience as a urologic surgeon, do you regularly work with women who have developed infections secondary to the presence of mesh, polypropylene transvaginal mesh, in the office?
MR. SNELL: Objection, lacks foundation.
A. I do.
Q. And have you treated those women?
A. I have.
Q. And have you managed their clinical

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complications?
A. I have.
Q. Does that include women who have been implanted with the TVT device?
A. It has.
Q. And when we were discussing pathology before, have you as a urologist who actually treats women look at the clinical complications of women who have a TVT device that has been explanted and related that to the pathology that you have received and report on?
A. Yes, I have.
Q. Okay. Now, you were also asked a few different questions about the warnings that you give patients when you implant polypropylene mesh made by Ethicon, correct?
A. Correct.
Q. And Mr. Snell liked to use the term "sling" when he was asking you those questions. Do you recall that at all?
MR. SNELL: Objection, misstates.
Go ahead.
A. I do.
Q. And I want to clarify.

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Were you referring to the TVT device, the TVT mesh and the trocars, the entire kit, when you were answering Mr. Snell's questions concerning implanting polypropylene mesh made by Ethicon?
A. No, I was not.
Q. Okay. And when is the last time you, actually, implanted any kind of polypropylene mesh made by Ethicon?
A. You know, I've been asked this a number of times before and I gave my best estimate as in the mid 200s and I -- but I don't have any specific recollection.
Q. Is it safe to say it's been about ten years?
A. Yes.
MR. SNELL: Objection, objection, vague.
Q. Now, when you were --
MR. SNELL: The witness just answered he doesn't know. It's speculation.
Q. When you were referring to the slings that Mr. Snell kept referring to, you weren't referring to the TVT made by Ethicon, correct?
MR. SNELL: Objection --

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A. Right.
MR. SNELL: -- misstates testimony.
Q. Were you referring to any other sling kit that was made by Ethicon?
A. No.
Q. Were you referring to the TVT-O device that was made by Ethicon?
A. No.
Q. Were you referring to the Secure device that was made by Ethicon?
A. No.
Q. Were you referring to the TVT Abbrevo device that was made by Ethicon?
A. No.
Q. Do you believe that there is a different risk profile for the hand-cut mesh that you implanted more than a decade ago and the TVT Ethicon device that you've offered your expert opinion on in this case?
MR. SNELL: Objection, beyond the scope.
A. I do.
Q. And do those require different surgical techniques?

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A. Yes.
Q. Okay. Now, you were also asked a number of questions by Mr. Snell about the methodology for selecting articles in your report. Do you recall that?
A. Yes, I do.
Q. In fact, we've heard a lot about it today. I want to ask you, specifically, something else.
What was the methodology that you used in developing the opinions that you hold in your expert report that was produced in this case as opposed to the "Nature" article?
A. The methodology --
MR. SNELL: Objection, asked and answered.
Go ahead.
A. The methodology was -- first, my own personal experience with mesh, with mesh complications and with my firsthand knowledge of what my peers and the medical community at large that I interact with, what their opinions were and what they knew about the potential of mesh to cause complications and what they knew about the science

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behind the theories that led to the use of mesh and their knowledge of the complications that had occurred in the past and were occurring during the present, whenever that was.
So the first part of my answer is my own personal experience with all of these things. The second part is my review of the medical literature and tempered with a third part is my rather unique awareness of the medical literature because I was editor and chief for so many years of the major journal that dealt with these kinds of things. And I was also either on the editorial board or a reviewer for the other medical journals that dealt with this. So I had a perspective of all of the quality of the studies that were submitted for peer review and the methodology and I think it gave me a unique perspective on understanding the differences between the methodology that they use for complications versus the methodology they use for safety -- excuse me, for efficacy.
Q. And, in fact, Table 1 that Mr. Snell asked you about in your "Nature" article, does that concern safety or does that concern efficacy?
A. That concerns safety. And it was

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only there -- we only --
Q. Can you take a look at the table again --
MR. SNELL: Don't interrupt the witness.
(There is a discussion off the record.)
THE WITNESS: May I?
MR. SNELL: Of course. Oh, I'm sorry.
A. Yes, efficacy.
Q. Okay.
A. Isn't that what -- I'm sorry. I thought that's what I said.
Q. That's okay.
A. Yeah.
Q. Now, in the literature review that you have performed for your expert report that you've offered here, did you include more articles that are referenced in your "Nature" article?
MR. SNELL: Objection, lacks foundation.
THE WITNESS: I'm sorry, can you read that back.
(Whereupon, the question is read back as

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follows:
"Question: Now, in the literature review that you have performed for your expert report that you've offered here, did you include more articles that are referenced in your 'Nature' article?")
MR. SNELL: Same objection.
Q. That are referenced in your "Nature" article.
A. I'm sorry, for the literature -- I'm sorry, I don't understand.
Q. Let me try again, if you're not understanding.
You have cited certain articles in your "Nature" article, correct?
A. Yes.
Q. And I think it numbers somewhere in the 300s; is that about right?
A. Yes.
Q. Okay. And you, also, have provided a reliance list in this case in connection with your expert report, correct?
A. Correct.
Q. Do you know whether it included more articles than you cited in your "Nature" article?

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A. I think it included less.
Q. And your reliance list itself -- do you have your expert report in front of you?
A. I do not.
MS. FITZPATRICK: Do you have a copy of the exhibit?
MR. SNELL: No, I don't have that one.
A. It's on my desk someplace.
Q. We'll wait.
(There is a discussion off the record.)
Q. Well, let me ask you this, Doctor, just to cut through it.
You provided a reliance list in connection with the articles that you reviewed in this report, correct?
A. I did.
Q. And is that an accurate representation of the number of articles that you have reviewed specific to your report in this TVT case?
MR. SNELL: Objection, lacks foundation.
A. Yes, it was -- is.

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Q. Okay. And that was something that you personally reviewed and you personally approved prior to submitting it --
A. Yes.
Q. -- correct?
And the articles that Mr. Snell has provided to you that he says are not on Table 1 of your "Nature" article, if those are included in your reliance list for the report that you offered in this case, would that be accurate to say that you have looked at those articles and considered them in connection with these opinions?
MR. SNELL: Objection, requires speculation.
A. Yes, it would.
Q. Okay. Now, you also talked about the quality of literature on pubovaginal slings. Do you recall that?
A. I do.
Q. And I believe you said that the quality of that literature was "poor." Do you remember saying that?
A. Yes.
Q. Okay. Is there sufficient evidence

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in your opinion in the literature to base the opinions that you've offered here on the safety and efficacy of the pubovaginal sling?
MR. SNELL: Objection, vague. The witness has already testified.
THE WITNESS: I'm sorry, read that back again.
(Whereupon, the question is read back as follows:
"Question: Is there sufficient evidence in your opinion in the literature to base the opinions that you've offered here on the safety and efficacy of the pubovaginal sling?")
MR. SNELL: Objection, vague, overbroad.
Go ahead.
A. Okay. For the safety -- excuse me.
For the efficacy, yes, and -- but my opinion for safety is based not only on the medical literature, which I've already said I think when it comes to safety is poor, but my review of what's not in the literature. So I suppose in a sense that's a review of the literature. So I'm going to say, yes, it is based on the medical literature.

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Q. Okay. Do you rely on anything else besides the published literature concerning your opinions on the safety and efficacy of the pubovaginal sling as set forth in your report?
MR. SNELL: Objection, vague, asked and answered.
A. Very very much so. And, in particular, for the last 20 years I've been running -- I've been either co-chairman or chairman or faculty member of courses that where in -- in which we always have sessions on complications. And we have whole sessions on complications of mesh slings. There's always, you know, half a day or, at least, an hour or two on mesh sling complications. We don't have -- this is even going back 25 years ago. We never had -- we never had such discussions of complications for autologous slings.
And, again, Burch's just weren't done that much in the environment that I was in. It would be restricted to autologous slings. There just wasn't concern about it. The complications from autologous slings where the sling was too tight or not and caused obstruction, which could be relatively easily fixed by cutting the sling, or it caused de novo

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overactive bladder symptoms. But there were never whole sections of seminars devoted to pelvic pain or pain after slings. It just didn't exist. So -- and it doesn't exist in the literature other than in a few, in my judgment, poorly done studies. So all that led me to believe that complications after mesh slings are serious and serious problems that occur often enough to capture the attention of both academics and doctors in practice. Whereas complications from autologous slings were pretty much limited to those two complications that I said.

MR. SNELL: [MOTION] I'm going to move to strike as nonresponsive. Also, move to strike speculative, speculative testimony about there was no concern of others -- no concern by others. I'm just making my record.

MS. FITZPATRICK: Would you also just put on the record why you believe you can move to strike a deposition answer, Burt? Can you give us the chapter and verse?

MR. SNELL: Because the witness should answer a question responsively whether I asked it or you asked it.

MS. FITZPATRICK: He did answer

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responsively.

So I object to Mr. Snell's meaningless motion to strike.

Q. Let's move onto a little bit of what Mr. Snell -- what I like to call the smoke and mirrors of his deposition practice here.

MR. SNELL: [MOTION] I move to strike attorney comment. That's not even a proper question.

Q. The article that you drafted in "Nature," can you read the title of that into the record, please.

A. "Safety Considerations for Synthetic Sling Surgery."

Q. And is it fair to say the primary thrust of the article that you published with your colleagues for "Nature" dealt with safety issues concerning the polypropylene midurethral sling like the TVT?

A. Yes.

Q. Okay. And Mr. Snell only asked you about a single table, that is, Table 1, in that article, correct?

MR. SNELL: Objection. Actually,

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that misstates my questioning.

A. I don't remember if that's the only thing he asked me about.

Q. Did he primarily ask you about what was and what was not included in Table 1, which is the table that concerns efficacy, and not safety?

MR. SNELL: I'm going to object. That misstates my questioning.

A. I do remember that being a main thrust, yes.

Q. So let's talk a little bit about some of those. For example, Mr. Snell asked you today whether an article called, "The Long-Term Outcomes of TVT and IVS Operations for Treatment of Female Stress Urinary Incontinence: Monofilament Versus Multifilament Polypropylene Tape" -- do you recall that?

A. I do.

Q. And he asked you whether that had been included in Table 1 -- it's, actually, Exhibit 25 -- that had been included in Table 1 concerning efficacy, correct?

A. Correct.

Q. What he didn't ask you, which I think

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is more pertinent is, did you cite this in Footnote 212 of your article concerning the safety and rely on this concerning safety conclusions you reached about the midurethral polypropylene study?

MR. SNELL: Objection, leading, argumentative.

A. Yes, I did.

Q. And, in fact, did you cite this article in connection with your opinions and recitation concerning both erosions and fistulas caused by polypropylene slings in women?

A. I did.

Q. The second one that Mr. Snell asked you about today was Exhibit No. 26, which was "Long-Term Results of the Tension-Free Vaginal Tape Procedure in an Unselected Group: A Seven-Year Follow-Up Study," correct?

A. Yes.

Q. Okay. And Mr. Snell, again, asked you why that wasn't included in the efficacy table, correct?

A. Correct.

Q. He didn't ask you whether it was included in your -- the main thrust of your article,

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which was the safety concerns that were raised by polypropylene midurethra slings, did he?
MR. SNELL: Objection, leading.
A. He did not.
Q. Okay. And if you look at Footnote No. 227 in your "Nature" article, did you, in fact, rely on and cite this particular article identified by Mr. Snell in part of your safety analysis?
A. I did.
Q. No. 27 is an article entitled, "Long-Term Efficacy of Tension-Free Vaginal Tape in the Management of Stress Urinary Incontinence in Women Efficacy at 5 and 7-year follow-up." Do you see that?
A. I do.
Q. And, once again, Mr. Snell asked you why this was not included in Table No. 1 concerning efficacy, correct?
A. Correct.
(There is a discussion off the record.)
Q. He did not ask you whether this particular article was cited in your "Nature" review concerning the safety aspects of polypropylene midurethral slings, did he?

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A. He did not.
Q. And, in fact, at Footnote No. 74, you cite to this very article in connection with your analysis of the safety of polypropylene midurethral slings, correct?
A. Yes.
Q. And, in fact, you looked at this article in connection with your opinions on bacterial cystitis, perforations, voiding dysfunction and urethral obstructions, correct?
A. Yes.
MR. SNELL: Leading.
Go ahead.
Q. There was also a discussion of Dr. Serati's article last week. Do you recall that?
A. Not specifically, no.
Q. Do you know whether you relied on Dr. Serati's article in your "Nature" review?
A. I don't know how to spell his name.
Q. S-e-r-a-t-i.
A. I do remember that now, yes. I mean, I remember reading it.
Q. And if you look at Footnote No. 18, which refers to Dr. Serati's article, is it fair to

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say that you relied on the article concerning the TVT-O for the treatment of stress urinary incontinence in your review article?
A. Yes, I did.
Q. Now, there was also a lot of discussion about why certain articles were included and excluded from Table 1 concerning efficacy.
The fact that they were not contained in exhibit or Table 1 concerning efficacy does not mean that you and your colleagues didn't consider them for your safety analysis, does it?
MR. SNELL: Objection, calls for speculation.
A. No, to the contrary. We cited it and did consider it for safety.
Q. Okay. And, with respect to Table 1, am I correct that you only included the most recent published article from a particular cohort and not all of the interim studies?
MR. SNELL: Actually, leading, objection.
A. Yes.
Q. And, for example, is it correct you only included Dr. Nilsson's 2013 paper, correct?

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A. That's correct.
Q. But you knew that there were earlier papers that came out from his cohort, correct?
MR. SNELL: Objection, leading.
Go ahead.
A. Yes. And my recollection is we even discussed those in the paper itself.
Q. Right. And you discussed those in connection with the safety considerations, correct?
A. Yes.
Q. But you only included the last paper in the efficacy considerations, correct?
A. Yes.
MR. SNELL: Objection, leading.
Go ahead.
Q. Despite the fact that some of those papers came out more than five years after the cohort was commenced, correct?
MR. SNELL: Objection, leading.
A. Yes.
Q. And was that because they were reporting on the safety cohort of women that were already discussed in the 2013 article?
A. Yes.

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Q. Okay. Now, Mr. Snell asked you a number of hypothetical questions about additional 10 studies or 12 studies that purportedly may not have been included in Table 1.

He didn't identify all of those articles for you, correct?

A. Correct.

Q. And, in the absence of the identification of those articles, you can't determine which articles, specifically, he's referring to, correct?

A. Correct.

Q. And you can't determine whether these hypothetical -- why these hypothetical -- let me...

You can't determine whether these hypothetical articles even exist, correct?

A. Correct.

Q. And you can't determine if they exist, why they were not included in the table in the absence of him identifying those, correct?

A. Yes.

Q. Now, did you consider and read more articles than you actually cited in your "Nature" review article?

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MR. SNELL: Objection, vague.

A. For -- for what? I don't understand the question.

Q. Fair enough. That was a bad question.

In your work dealing with women who have pelvic mesh complications, writing articles, reviewing articles for journals and in your work in preparing your expert reports in this case, have you considered more articles than are actually cited just in the "Nature" article itself?

A. I have.

Q. That's all that I have.

MR. SNELL: Alright. I just have a few follow-up. And let's stop to take a break. I want to find something in here real quick.

(Recess taken 3:39 to 3:42 p.m.)

EXAMINATION BY MR. SNELL:

Q. Doctor, a follow-up on some of the questions you were asked, some questions about pathology.

Am I correct that you're not credentialed here at your hospital to read and interpret pathology slides that --

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MS. FITZPATRICK: Objection.

Q. -- provide --

A. That's correct.

MS. FITZPATRICK: Objection, asked and answered.

Q. And you don't write pathology reports?

MS. FITZPATRICK: Objection, asked and answered.

A. That's correct.

Q. And you have not published the findings of pathology reports for your patients, correct?

MS. FITZPATRICK: Objection.

A. That's correct.

Q. Meaning, you haven't written an article submitted to peer review as to the pathology findings of your patients, correct?

MS. FITZPATRICK: Objection.

A. Correct.

Q. You haven't done that for your pubovaginal sling patients, correct?

A. Correct.

Q. And you haven't done that for

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midurethral sling patients, correct?

A. Correct.

MS. FITZPATRICK: Objection, vague.

Q. You mentioned that you were an editor of a journal and that you believe had some bearing on your opinions.

Remind me of what journal that was? Was that the Journal of Neurourology and Voiding Dysfunction?

A. And Uro --

MS. FITZPATRICK: Objection.

A. It's called Neurourology and Uro Dynamics.

Q. Let me back up one minute.

What journal did you refer to to which you were an editor?

A. Neurourology and Uro Dynamics.

Q. So you would have reviewed studies submitted to that -- strike that.

You would have reviewed articles submitted to that journal?

MS. FITZPATRICK: Objection, lacks timeframe, lacks a foundation.

A. Yes, to that journal and also I

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mentioned many other journals as well.
Q. When you were the editor of that particular journal, did you review all of the articles submitted to it?
MS. FITZPATRICK: Objection, lacks foundation.
A. I reviewed all of the abstracts and then depending upon the abstracts, I would make a judgment on whether or not I wanted to review the paper in detail. I was -- I was never a reviewer for an article unless I was asked to be by one of the editors. But I reviewed -- so I wasn't an official reviewer, but I reviewed, I mean, virtually all the articles on mesh because that was an interest of mine and I had final say over publication. So anytime there was a discrepancy, then I would review the article.
Q. Is it your contention that every article that came out of that journal while you were editor is methodologically sound?
A. I don't --
MS. FITZPATRICK: Objection.
A. No. It's not my contention at all.
Q. Mistakes could have been made during

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the editorial process while you were editor of that journal, right?
MS. FITZPATRICK: Objection, beyond the scope, lacks a foundation, hypothetical.
A. "Mistakes" are always possible. But the problems -- the "mistakes" are possible, but more often than not if a paper reported on efficacy -- if the primary objective of the paper was to report on efficacy and that was acceptable, then we -- in general, they wouldn't reject the article because of that and they would let the complication part stand because the complications they do report are valuable contributions to the literature. If we didn't do that, then there would be no complications reported to the literature and that would be even worse. I don't consider those "mistakes." I consider those, you know, prudent and practical compromises that editorial staff has to take.
Q. So complications being reported in the literature, is that a beneficial thing in your opinion?
MS. FITZPATRICK: Objection, hypothetical, lacks -- hang on -- hypothetical, lacks foundation, beyond the scope of his expert

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opinion in this case.
A. Reporting complications is always valuable, but it doesn't give you a handle on what the incidence of the complications are or the likelihood of someone developing a complication.
Q. So, you know Ed McGuire, right?
A. I do.
Q. Have you read some of his articles on autologous pubovaginal slings?
A. I have.
Q. Have you seen they actually had sling exposures -- strike that -- sling erosions with the autologous pubovaginal sling, right?
A. I'm not aware of that.
Q. Okay.
A. It doesn't mean it didn't happen.
Q. Fair enough.
The Journal of Neurourology, why did they ask you to step down as editor at the meeting in Italy?
MS. FITZPATRICK: Objection, lacks foundation, hypothetical, assumes facts not in evidence.
MR. SNELL: It's not hypothetical.

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MS. FITZPATRICK: You've got no foundation.
A. I'm not aware that they asked me to step down at the meeting in Italy.
Q. Okay. Did they ask you to step down as editor of that journal?
A. Who is -- I don't know who you mean by "they."
Q. Was there a vote of confidence on you in your role as editor of that journal?
A. I'm not aware of that.
Q. And it's your contention -- were you asked to step down as editor of that journal?
A. By whom?
Q. By anyone.
A. There were people -- like anybody else, there were people that would like to see me not be editor. But I think you can say that about anybody in a public position.
Q. But you did step down from that journal, correct?
A. After 20 something years, yes.
Q. And it was following a vote at a meeting in Italy; is that correct or not?

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MS. FITZPATRICK: Objection, asked and answered, hypothetical, assumes facts not in evidence. This has already been responded to by Dr. Blaivas and this is pure harassment at this point.

A. You know what, I'm not aware of that. I mean...

Q. Okay. That's fair enough.

When you were editor of that journal, did you review the minutes of meetings coming out of board meetings and other committee meetings?

A. Board meetings of whom?

Q. Of members of the journal, the editorial staff.

A. Of course.

MS. FITZPATRICK: Hang on. Give me a chance.

THE WITNESS: Okay.

MS. FITZPATRICK: Objection, beyond the scope, irrelevant to what it is we're discussing here, hypothetical.

(There is a discussion off the record.)

MR. SNELL: I'm just going to be quick.

Q. Plaintiffs' counsel asked you some

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questions about the review and she seems to insinuate that I didn't ask you about anything other than Table 1, the long-term.

But, Doctor, actually, you and I discussed quite a bit Table 3, "Complications of Retropubic Slings," didn't we?

A. Yes, we did.

Q. And that's where you reported the less than 1 percent rate of women who had pain lasting six weeks or more with the TVT, right?

A. I didn't report that. I read what other reportedly constructed studies have shown.

Q. That's what you wrote down in your paper, though, correct?

A. We -- yes, I just answered that.

Q. Okay. And you and I discussed vaginal exposures, too, that you reviewed, right?

A. Yes.

Q. And you were asked questions about infection and you and I also discussed and you wrote in your review that the rate of serious infection in combination with bowel perforations was less than what, Doctor? It's highlighted on the right side.

A. Of about 0.1 percent.

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Q. Do you recall us having a discussion about that during my initial questioning?

A. I did, I do.

Q. Okay. Can I see that back really quick?

A. Its yours.

Q. Well, we're sharing it.

Plaintiffs' counsel just showed you the Footnote 18 by Serati, TVT-O five-year follow-up. Do you recall that?

A. I do.

Q. Do you recall that the article, actually, showed you was the ten-year TVT retropubic follow-up, correct?

A. I don't recall it independently, but I'll accept it from a...

Q. And we'll stop. I think I might be done.

You mentioned that sometimes and then very frequently you would ask for a revised pathology report to be issued concerning one of your patients. Do you recall giving that testimony?

A. Yes.

Q. In what percentages of your cases do

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you ask for revised pathology reports?

A. I would say in most cases I have a question for them. It doesn't always relate to asking them to revise it. But, I mean, the problem is they don't -- you know, they don't routinely do things that would be useful -- would be useful for, basically, for our research because we're not, you know, they're looking -- they look at the pathology differently than we do. I mean, in fairness, I don't think anybody is doing anything wrong. I think their goal of looking at pathology is to make sure that there's not cancer or, in fact, we're giving them a proper specimen. And our goal is to try to understand better about the physiology and pathophysiology of all these things. But it really doesn't necessarily -- it doesn't change how we treat the patient. It changes how we understand how they got there.

Q. Yeah.

A. So they don't -- it's just a different frame of reference.

MR. SNELL: [MOTION] I'm going to, very respectfully, move to strike as nonresponsive.

MS. FITZPATRICK: I'm going to object

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to the motion to strike.
MR. SNELL: Can you reread the question to the Doctor.
Q. And I'm focused on what is the percent. But I'll let Madam court reporter read it back.
(Whereupon, the question is read back as follows:
"Question: In what percentages of your cases, do you ask for revised pathology reports?")
A. I don't have independent knowledge, but I would say less than half but more than single-digit percents. I just couldn't estimate better than that.
Q. Okay. Okay. I'm done. Thank you.
MS. FITZPATRICK: I have one question based on that, maybe two.
EXAMINATION BY MS. FITZPATRICK:
Q. Dr. Blaivas, have you personally ever seen a woman who had an erosion with a pubovaginal or an autologous sling?
A. No.
Q. Have you talked to your colleagues about any problems that they have had with erosion

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caused by pubovaginal or autologous slings?
A. Never.
Q. Do you believe that an erosion is a common complication or even a rare complication of pubovaginal or autologous sling?
MR. SNELL: Objection.
A. No, I do not.
Q. Okay. And why not?
A. I answered part of it before. Because, you know, we -- over the years we probably -- I would say I have lectured before just in small groups I would say, at least, 5,000 different urologists and gynecologists, which is, you know, by today's numbers half of all urologists in the country and it never once came up. And we get questions about -- we get questions about mesh fistulas, which by my own account is less than 1 percent. So people, actually, ask me, well, how do you manage mesh fistulas?
It's inconceivable to me that if this was a common problem, not one person ever would have asked me about an erosion and it was never ever not once brought up in any of our meetings. I've never seen it ever once presented at any of our national or

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international meetings. And every one of them has something about mesh complications and mesh erosion so...
Q. Okay. That's all that I have.
MR. SNELL: I'm going to follow up on that.
EXAMINATION BY MR. SNELL:
Q. Well, I showed you in your own AUA guidelines Table A16 revised 2012 where you and a whole bunch of other urologists reported autologous fascia without bone anchors.
So that's a non-synthetic procedure, right?
A. Yes.
Q. And you reported, "erosion extrusion 1 percent," and below that it says, "erosion extrusion into the urethral-bladder 2 percent."
So it has been reported even by you, correct?
A. I don't believe any of the people -- this was -- yes, it's been reported. But I don't believe that any of us acknowledged that it happens with that frequency.
The problem is I alluded to before is that we were constrained by the AUA -- overall AUA

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guidelines panel -- by the overall guidelines panel committee on a certain methodology to, you know, in our reporting. So, if these things were reported in the literature, we couldn't say that they -- we couldn't ignore it.
But thanks to your questioning from last time, I had the opportunity to go back and read some of the papers that actually alluded to this. And what I found was that many of the studies that used -- many of the reported studies about autologous slings eroding or perforating used a methodology -- a flawed methodology that I've been critical of with -- that the TVT introduced. And that is blind passage of trocars to pass the instruments to put the sling in place. So what I believe happened is the newer studies using autologous slings utilized a flawed technique introduced by the TVT and, therefore, suffered some of the same complications that the TVT -- that the TVT had. When you compare -- when you look at the studies that used what we call full-length autologous slings, in using the technique, for example, that I described, I don't believe there is a single case report in the world literature about that. And even if there was, as I

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already mentioned, it's extraordinarily rare and of little consequence and even if every one of these -- I don't believe they were, but even if every one of these reported complications was a legitimate complication of an autologous sling, even if that were the case, the repercussions are almost nothing. All you -- compared to a mesh sling. So the net effect is what I already testified to a moment ago. So I'm not going to repeat it.

Q. Well, Doctor, I think you just said that the blind passage of instruments or trocars was introduced by TVT.

You and I both know that surgeons were passing blindly surgical instruments to put in autologous pubovaginal sling long before TVT, right?

MS. FITZPATRICK: Objection, mischaracterizes and misstates the testimony.

A. Not -- well, there's a difference --

Q. Can you answer my question yes or no?

A. Not since -- to my knowledge, the overwhelming majority -- I can't say never. But the overwhelming majority of autologous slings were done by the technique that was described either by Dr. McGuire or myself. And neither of us used trocars

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and things like that. We used -- the dissection was done with our finger -- the way -- I've already testified to the way it was done. So now the Roz (phonetic) technique did -- the Roz (phonetic) technique not for slings but the Roz (phonetic) technique for -- I'm trying to -- that he used for his repair -- for his incontinence operations, that did use a small trocar and that did have that complication sometimes. But that's not the technique for autologous slings.

Q. You were using needles blindly for your autologous pubovaginal slings long before TVT, right?

A. I never --

MS. FITZPATRICK: Objection, mischaracterizes the testimony.

A. The answer is, no, I don't believe I ever used one.

Q. What instrument did you use? I thought you told me you used Stamey needle --

A. No.

Q. -- or some other type of needle to pass your sling to go down and pull it back up.

A. Okay.

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MS. FITZPATRICK: Objection, mischaracterizes the testimony.

A. I understand the question.

I used Stamey needle only for the synthetic sling when I temporarily bought into the idea that this might be a good technique. I never once ever used anything other than something called a long Debakey clamp, which is not a trocar, which does not have a point. That's the only instrument I've ever used for an autologous sling.

Q. You said you read some of these papers on autologous slings. What are the names of those papers that you read?

A. I don't have an independent recollection of it right new.

MS. FITZPATRICK: Objection.

Can we check the time?

Q. How many of them did you read?

A. Five.

MS. FITZPATRICK: Let's take a minute to check the time.

(There is a discussion off the record.)

A. I want to correct my last answer. I think I said five at the end. I didn't mean -- I do

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have a recollection. I read all of the references relating to erosions that were referenced in the Schimpf article that you brought to my attention last time. But I don't remember right now the individual papers.

Q. Did you go back and read all the articles cited in the AUA paper?

A. No, but I did review some of them.

Q. You mentioned that you do a full-length autologous sling. When you say, "full-length," what do you mean by that?

A. It means that it's long enough -- there isn't a specified length, but it's long enough to go from well into the retropubic space on one side and around to the other side. And, usually, it goes to just underneath the rectus fascia on one side to just underneath the rectus fascia on the other side.

Q. Is there an average length? Are we talking 10 centimeters, 20 centimeters?

A. Yeah, I would say -- I would say average maybe 10 or 12.

Q. Okay.

A. It depends on how big the person is.